

## PART 124—PATENT TERM RESTORATION

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### Subpart A—General Provisions

#### § 124.1 Scope.

(a) This part sets forth procedures and requirements for APHIS review of applications for the extension of the term of certain patents for veterinary biological products pursuant to 35 U.S.C. 156—Extension of patent term. Responsibilities of APHIS include:

(1) Assisting PTO in determining eligibility for patent term restoration;

(2) Determining the length of a product's regulatory review period;

(3) If petitioned, reviewing and ruling on due diligence challenges to APHIS's regulatory review period determinations; and

(4) Conducting hearings to review initial APHIS findings on due diligence challenges.

(b) The regulations in this part are designed to be used in conjunction with regulations issued by PTO concerning patent term extension which may be found at 37 CFR 1.710 through 1.791.

[58 FR 11369, Feb. 25, 1993, as amended at 64 FR 43045, Aug. 9, 1999]

#### § 124.2 Definitions.

*Animal and Plant Health Inspection Service (APHIS).* The agency in the Department of Agriculture responsible for licensing veterinary biological products under the Virus-Serum-Toxin Act.

*Applicant.* Any person who submits an application or an amendment or supplement to an application under 35 U.S.C. 156 seeking extension of the term of a patent.

*Due diligence petition.* A petition submitted under § 124.30 of this part.

*Informal hearing.* A hearing that is not subject to the provisions of 5 U.S.C. 554, 556, and 557 and that is conducted as provided in 21 U.S.C. 321(x).

*License applicant.* Any person who, in accordance with part 102 of this chapter, submits an application to the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture for a U.S. Veterinary Biological Product License.

*Patent.* A patent issued by the Patent and Trademark Office of the United States Department of Commerce.

*Person.* Any individual, firm, partnership, corporation, company, association, educational institution, State or local government agency, or other organized group of any of the foregoing, or any agent, officer, or employee of any thereof.

*PTO.* The Patent and Trademark Office of the United States Department of Commerce.

[58 FR 11369, Feb. 25, 1993, as amended at 68 FR 6346, Feb. 7, 2003]

### Subpart B—Eligibility Assistance

#### § 124.10 APHIS liaison with PTO.

Upon receipt of a copy of an application for extension of the term of a veterinary biologic patent from PTO, APHIS will assist PTO in determining whether a patent related to a biological product is eligible for patent term extension by:

(a)(1) Verifying whether the product was subject to a regulatory review period before its commercial marketing or use;

(2) Determining whether the permission for commercial marketing or use of the product after the regulatory review period was the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred, and, if so, whether it was the first permitted commercial marketing or use of the veterinary biological product for administration to a food-producing animal;

(3) Ascertaining whether the patent term restoration application was submitted within 60 days after the product was approved for marketing or use; and

(4) Providing such other information as may be necessary and relevant to PTO's determination of whether a patent related to a product is eligible for patent term restoration.

(b) APHIS will notify PTO of its findings in writing, send a copy of this notification to the applicant, and make a copy available for public inspection in room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

### Subpart C—Regulatory Review Period

#### § 124.20 Patent term extension calculation.

(a) As provided in 37 CFR 1.779 of PTO's regulations, in order to determine a product's regulatory review period, APHIS will review the information in each application to determine the lengths of the following phases of the review period, and will then find their sum:

(1) The number of days in the period beginning on the date authorization to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was initially submitted under the Virus-Serum-Toxin Act; and

(2) The number of days in the period beginning on the date an application for a license was initially submitted

for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(b) A license application is "initially submitted" on the date it contains sufficient information to allow APHIS to commence review of the application. A product license is issued on the date of the APHIS letter informing the applicant of the issuance. The issuance of a license releases the product for commercial marketing or use.

#### § 124.21 Regulatory review period determination.

(a) Not later than 30 days after the receipt of an application from PTO, APHIS shall determine the regulatory review period. Once the regulatory review period for a product has been determined, APHIS will notify PTO in writing of the determination, send a copy of the determination to the applicant, and make a copy available for public inspection in room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

(b) APHIS will also publish a notice of the regulatory review period determination in the FEDERAL REGISTER. The notice will include the following:

- (1) The name of the applicant;
- (2) The trade name and true name of the product;
- (3) The number of the patent for which an extension of the term is sought;
- (4) The approved indications or uses for the product;
- (5) The regulatory review period determination, including a statement of the length of each phase of the review period and the dates used in calculating each phase.

#### § 124.22 Revision of regulatory review period determination.

(a) Any interested person may request a revision of the regulatory review period determination within the 30 day period beginning on its publication in the FEDERAL REGISTER. The request must be sent to the Director, Center for Veterinary Biologics, Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, IA

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50010—8197. The request must specify the following:

- (1) The identity of the product;
- (2) The identity of the applicant for patent term restoration;
- (3) The docket number of the FEDERAL REGISTER notice announcing the regulatory review period determination; and
- (4) The basis for the request for revision, including any documentary evidence.

(b) If APHIS decides to revise its prior determination, APHIS will notify PTO of the decision, and will send a copy of notification to the applicant and the person requesting the revision (if different from the applicant) with a request for comments within 10 days of notification. If no comment on the proposed revision is received, APHIS will publish the revision in the FEDERAL REGISTER, and include a statement giving the reasons for the revision. If comment is received, APHIS will make a final determination regarding the revision based on such comment and will then publish the revision in the FEDERAL REGISTER, giving reasons for its determination.

[59 FR 11369, Feb. 25, 1993, as amended at 59 FR 67617, Dec. 30, 1994; 64 FR 43045, Aug. 9, 1999]

## § 124.23 Final action on regulatory review period determination.

APHIS will consider its regulatory review period determination to be final upon expiration of the 180-day period for filing a due diligence petition under § 124.30 unless it receives:

- (a) New information from PTO records, or APHIS records, that affects the regulatory review period determination;
- (b) A request under § 124.22 for revision of the regulatory review period determination;
- (c) A due diligence petition filed under § 124.30; or
- (d) A request for a hearing filed under § 124.40.

[58 FR 11369, Feb. 25, 1993; 58 FR 29028, May 18, 1993]

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### Subpart D—Due Diligence Petitions

#### § 124.30 Filing, format, and content of petitions.

(a) Any interested person may file a petition with APHIS, no later than 180 days after the publication of a regulatory review period determination under § 124.21, alleging that a license applicant did not act with due diligence in seeking APHIS approval of the product during the regulatory review period.

(b) The petition must be filed with APHIS under the docket number of the FEDERAL REGISTER notice of the agency's regulatory review period determination. The petition must contain any additional information required by this subpart.

(c) The petition must allege that the applicant failed to act with due diligence sometime during the regulatory review period and must set forth sufficient facts to merit an investigation by APHIS of whether the applicant acted with due diligence.

(d) The petition must contain a certification that the petitioner has served a true and complete copy of the petition on interested parties by certified or registered mail (return receipt requested) or by personal delivery.

#### § 124.31 Applicant response to petition.

(a) The applicant may file with APHIS a written response to the petition no later than 20 days after the applicant's receipt of a copy of the petition.

(b) The applicant's response may present additional facts and circumstances to address the assertions in the petition, but shall be limited to the issue of whether the applicant acted with due diligence during the regulatory review period. The applicant's response may include documents that were not in the original patent term extension application.

(c) If the applicant does not respond to the petition, APHIS will decide the matter on the basis of the information submitted in the patent term restoration application, the due diligence petition, and APHIS records.

**§ 124.32 APHIS action on petition.**

(a) Within 90 days after APHIS receives a petition filed under § 124.30, the Under Secretary for Marketing and Regulatory Programs shall make a determination under paragraphs (b) or (c) of this section or under § 124.33 whether the applicant acted with due diligence during the regulatory review period. APHIS will publish its determination in the FEDERAL REGISTER together with factual and legal basis for the determination, notify PTO of the determination in writing, and send copies of the determination to PTO, the applicant, and the petitioner.

(b) APHIS may deny a due diligence petition without considering the merits of the petition if:

(1) The petition is not filed in accordance with § 124.30;

(2) The petition does not contain information or allegations upon which APHIS may reasonably determine that the applicant did not act with due diligence during the applicable regulatory review period; or

(3) The petition fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence so that, even if the petition were granted, the petition would not affect the maximum patent term extension which the applicant is entitled to under 35 U.S.C. 156.

[59 FR 11369, Feb. 25, 1993, as amended at 64 FR 43045, Aug. 9, 1999]

**§ 124.33 Standard of due diligence.**

(a) In determining the due diligence of an applicant, APHIS will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited the degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. APHIS will take into consideration all relevant factors, such as the amount of time between the approval of an experimental use permit and licensure of the veterinary biological product.

(b) For purposes of this Part, the actions of the marketing applicant shall be imputed to the applicant for patent

term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant shall be imputed to the applicant for patent term restoration.

**Subpart E—Due Diligence Hearing****§ 124.40 Request for hearing.**

(a) Any interested person may request, within 60 days beginning on the date of publication of a due diligence determination by APHIS in accordance with § 124.32, that APHIS conduct an informal hearing on the due diligence determination.

(b) The request for a hearing must:

(1) Be in writing;

(2) Contain the docket number of the FEDERAL REGISTER notice of APHIS's regulatory review period determination;

(3) Be delivered to the Director, Center for Veterinary Biologics, Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, IA 50010—8197.

(4) Contain a full statement of facts upon which the request for hearing is based;

(5) Contain the name, the address, and the principal place of business of the person requesting the hearing; and

(6) Contain a certification that the person requesting the hearing has served a true and complete copy of the request upon the petitioner of the due diligence determination and the applicant for patent term extension by certified or registered mail (return receipt requested) or by personal service.

(c) The request must state whether the requesting party seeks a hearing not later than 30 days after the date APHIS receives the request, or, at the request of the person making the request, not later than 60 days after such date.

[58 FR 11369, Feb. 25, 1993, as amended at 59 FR 67617, Dec. 30, 1994; 64 FR 43045, Aug. 9, 1999]

**§ 124.41 Notice of hearing.**

No later than ten days before the hearing, APHIS will notify the requesting party, the applicant, the petitioner, and any other interested person of the date, time, and location of the hearing.

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### § 124.42 Hearing procedure.

(a) The presiding officer shall be appointed by the Administrator of APHIS from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(b) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(c) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and any general summary of the information which will be presented at the hearing in support of such action.

(d) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral and written information relevant to such action.

(e) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the

presiding officer's report of the hearing.

(f) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(g) The due diligence hearing will be conducted in accordance with rules of practice adopted for the proceeding. APHIS will provide the requesting party, the applicant, and the petitioner with an opportunity to participate as a party in the hearing. The standard of due diligence set forth in §124.33 will apply at the hearing. The party requesting the due diligence hearing will have the burden of proof at the hearing.

### § 124.43 Administrative decision.

Within 30 days after completion of the due diligence hearing, the Under Secretary for Marketing and Regulatory Programs, taking into consideration the recommendation of the Administrator, will affirm or revise the determination made under §124.32. APHIS will publish the due diligence redetermination in the FEDERAL REGISTER, notify PTO of the redetermination, and send copies of the notice to PTO and the requesting party, the applicant, and the petitioner.

[59 FR 11369, Feb. 25, 1993, as amended at 64 FR 43045, Aug. 9, 1999]